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| MUMMERT, STEPHANIE KANE | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,378

Applicant(s)

LI ET AL.

Examiner

STEPHANIE K. MUMMERT

Art Unit

1637

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23, 24, 26-28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23, 24, 26-28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/28/09/7/6/09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 6, 2009 has been entered.

Applicant's amendment filed on July 6, 2009 is acknowledged and has been entered. Claims 1-3, 5, 8, 23-24, 26-28 have been amended. Claims 22, 25, 29 have been canceled. Claims 1-21, 23-24, 26-28 and 30 are pending. Claims 31-74 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 1-21, 23-24, 26-28 and 30 are discussed in this Office action.

All of the amendments and arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is made NON-FINAL.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on August 28, 2009 and July 6, 2009 were filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Previous Grounds of Rejection

The rejections over claims as being anticipated by Fodor have been withdrawn in view of the amendment to the claims.

Claim Interpretation

The claims are drawn to a chip comprising oligonucleotide probes that comprise at least 10 nucleotides complementary to a particular nucleotide sequence. Therefore, the claims will be given a broad interpretation based specifically on the "at least 10 nucleotides" limitation. For example, Fodor will be applied broadly over the majority of the claims because the reference teaches an array comprising all possible 10-mers, which therefore would inherently include those sequences which are specific for SARS-CoV, non-SARS-CoV, etc.

The term "SARS-like symptoms" is not explicitly defined in the specification. Instead, the term is referred in general terms, such as "The main symptoms for SARS patients include fever (greater than 38° C.), headache, body aches. After 2-7 days of illness, patients may develop a dry, nonproductive cough that may be accompanied with breathing difficulty (p. 1, lines 10-13)". Furthermore, while certain viruses were listed as organisms capable of causing "SARS-like symptoms" (p. 42, see also Table 15), due to the breadth of the term "SARS-like" and the

generality of the symptoms listed above, the term is being given the broadest reasonable interpretation as reading on any organism that causes symptoms such as fever and headaches.

The term “organism damaging the human immune system” is not explicitly defined in the specification. Instead, the term is referred to as “In some embodiments, the non-SARS-CoV infectious organism is an infectious organism damaging an infectious host's immune system. Such organism includes, but not limited to, a hepatitis virus, a transfusion transmitting virus (TTV), a human immunodeficiency virus (HIV), a parvovirus, a human cytomegalovirus (HCMV), an Epstein-Barr virus (EBV) and a *treponema palidum*. The hepatitis virus can be hepatitis virus A (HAV), hepatitis virus B (HBV), hepatitis virus C (HCV), hepatitis virus D (HDV), hepatitis virus E (HEV), or hepatitis virus G (HGV) ” (p. 38, see also Table 16, where a variety of organisms are listed). While certain viruses are listed as being capable of damaging the immune system, the specification also clearly states that the list is “not limited to” these choices. Therefore, due to the lack of explicit definition or further information regarding what constitutes “damage”, the term will be interpreted as reading on any virus.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1637

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 and 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/556182 (the "182 application" herein). Although the conflicting claims are not identical, they are not patentably distinct from each other because while the claims are not identical, the claims of the copending application are directed to obvious variants of the instant claims. The claims of the instant case and the copending claims are nearly identical. The difference lies in the inclusion of limitations in a different order in the two sets of claims. For example, claim 1 of the copending application is directed to a chip for assaying SARS-CoV which incorporates at least two probes which comprise at least 10 nucleotides complementary to at least two different sequences of SARS-CoV, while the instant claim 1 is directed to a chip for assaying SARS-CoV which incorporates a probe which comprise at least 10 nucleotides complementary to SARS-CoV and one or more other probes which are complementary to a nucleotide sequence of a non-SARS-CoV infectious organism. However, it is noted that these differing limitations between the instant case and the copending '182 application, are in fact present in different claims. In the instant case, claim 2 is directed to at least two oligonucleotides complementary to two different SARS-CoV sequences, as required in claim 1 of the copending application. In the copending application, claim 19 is directed to an oligonucleotide probe complementary to a nucleotide

sequence of a coronavirus not related to SARS-CoV, as required in the instant claim 1. The remaining dependent limitations to conserved and variable regions of the SARS-CoV genome are shared almost verbatim between the two copending applications and therefore the claims are obvious over the copending '182 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 15, 21 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Shi et al. (Chinese Science Bulletin, June 2003, vol. 48, no. 12, p. 1165-1169) as evidenced by Marra et al. (Science, 2003, vol. 300, p. 1399-1404; epub May 2003) and Koectters et al. (Virology, 1999, 264(2): p. 398-409). Shi teaches an oligonucleotide microarray in SARS coronavirus detection (Abstract).

With regard to claim 1, Shi teaches a chip for assaying for a coronavirus causing the severe acute respiratory syndrome (SARS-CoV) and a non-SARS-CoV infectious organism, which chip comprises a support suitable for use in nucleic acid hybridization having immobilized thereon an oligonucleotide probe complementary to a nucleotide sequence of SARS-CoV genome, said nucleotide sequence comprising at least 50 nucleotides, and one or more of the following oligonucleotide probe(s) (p. 1168, col. 2, 'design of the oligos and microarray' heading, Figure 1 and Table 1, where the specific oligonucleotide sequences complementary to SARS-CoV are included; Abstract, where the array comprises 60-mers,):

- a) an oligonucleotide probe complementary to a nucleotide sequence of a non-SARS-CoV infectious organism causing SARS-like symptoms, said nucleotide sequence comprising at least 50 nucleotides, wherein the non-SARS-CoV infectious organism causing SARS-like symptoms is selected from the group consisting of a human coronavirus 229E, a human coronavirus OC43, a human enteric coronavirus, an influenza virus, a parainfluenza virus, a respiratory syncytial virus, a human metapneumovirus, an adenovirus, a mycoplasma pneumonia, a chlamydia pneumonia, a measles virus and a rubella virus;
- b) an oligonucleotide probe complementary to a nucleotide sequence of a non-SARS-CoV infectious organism damaging the human's immune system, said nucleotide sequence comprising at least 50 nucleotides (Abstract, where the array comprises 60-mers, Table 1)

wherein the non-SARS-CoV infectious organism damaging the human immune system is selected from the group consisting of hepatitis virus, a transfusion transmitting virus (TTV), a human immunodeficiency virus (HIV), a parvovirus, a human cytomegalovirus (HCMV), an Epstein-Barr virus (EBV) and a Treponema pallidum (where oligo 10 is a sequence that is

complementary to multiple non-SARS-CoV organisms, including murine hepatitis virus, which is damaging to a human immune system as evidenced by Koettters, Abstract, where it is noted that murine hepatitis virus can infect human cells).

With regard to claim 2, Shi teaches an embodiment of claim 1, which chip comprises a support suitable for use in nucleic acid hybridization having immobilized thereon at least two oligonucleotide probes complementary to at least two different nucleotide sequences of SARS-CoV genome, each of said two different nucleotide sequences comprising at least 10 nucleotides (p. 1168, col. 2, 'design of the oligos and microarray' heading, Figure 1 and Table 1, where the specific oligonucleotide sequences complementary to SARS-CoV are included).

With regard to claim 3, Shi teaches an embodiment of claim 2, wherein the at least two different nucleotide sequences of SARS-CoV genome comprises:

- a) a nucleotide sequence of at least 50 nucleotides located within a conserved region of SARS-CoV genome and a nucleotide sequence of at least 50 nucleotides (Abstract, where the array comprises 60-mers, Table 1) located within a variable region of SARS-CoV genome (Table 1, oligo 2, 16, 12, 9, etc. which are directed to the replicase 1A sequence, as evidenced by Marra et al, Figure 1, where the replicase 1A sequence falls between 265-13,398, which is a conserved region, p. 1401, col. 2); or
- b) a nucleotide sequence of at least 50 nucleotides (Abstract, where the array comprises 60-mers, Table 1) located within a structural protein coding gene of SARS-CoV genome and a nucleotide sequence of at least 50 nucleotides located within a non-structural protein coding gene of SARS-CoV genome (Table 1, oligo 2, 16, 12, 9, etc. which are directed to the replicase 1A sequence, as

evidenced by Marra et al, Figure 1, where the replicase 1A sequence falls between 265-13,398, which is a conserved region, p. 1401, col. 2).

With regard to claim 4, Shi teaches an embodiment of claim 2, which further comprises:

- a) at least one of the following three oligonucleotide probes: an immobilization control probe that is labeled and does not participate in any hybridization reaction when a sample containing or suspected of containing of a SARS-CoV or a non-SARS-CoV infectious organism is contacted with the chip, a positive control probe that is not complementary to any sequence of a SARS-CoV or non-SARS-CoV infectious organism but is complementary to a sequence contained in the sample not found in the SARS-CoV or the non-SARS-CoV infectious organism and a negative control probe that is not complementary to any nucleotide sequence contained in the sample (Figure 1, where there were negative control spots included); and
- b) a blank spot (Figure 1, where there were empty control spots or blank spots).

With regard to claim 5, Shi teaches an embodiment of claim 2, which comprises at least two oligonucleotide probes complementary to two different nucleotide sequences of at least 50 nucleotides (Abstract, where the array comprises 60-mers, Table 1), respectively, located within a conserved region of SARS-CoV genome, located within a structural protein coding gene of SARS-CoV genome or located within a non-structural protein coding gene of SARS-CoV genome (p. 1168, col. 2, 'design of the oligos and microarray' heading, Figure 1 and Table 1, where the specific oligonucleotide sequences complementary to SARS-CoV are included; Table 1, oligo 2, 16, 12, 9, etc. which are directed to the replicase 1A sequence, as evidenced by Marra et al, Figure 1, where the replicase 1A sequence falls between 265-13,398, which is a conserved region, p. 1401, col. 2).

With regard to claim 6, Shi teaches an embodiment of claim 5, wherein:

- a) the conserved region of S ARS-CoV genome is a region located within the Replicase 1A or 1B gene or the Nucleocapsid (N-) gene of SARS-CoV;
- b) the structural protein coding gene of SARS-CoV genome is a gene encoding the Spike glycoprotein (S), the small envelope protein (E) or the Nucleocapsid protein (N); or c) the non-structural protein coding gene of SARS-CoV genome is a gene encoding the Replicase 1A or 1B (Table 1, oligo 2, 16, 12, 9, etc. which are directed to the replicase 1A sequence, as evidenced by Marra et al, Figure 1, where the replicase 1A sequence falls between 265-13,398, which is a conserved region, p. 1401, col. 2).

With regard to claim 7, Shi teaches an embodiment of claim 3, wherein the variable region of SARS-CoV genome is a region located within the Spike glycoprotein (S) gene of SARS-CoV (Table 1, oligo 28 and oligo 05, which are directed to spike glycoprotein, as evidenced by Marra et al., Figure 1, where the Spike glycoprotein falls between 21,492-25,259).

With regard to claim 8, Shi teaches an embodiment of claim 2, which comprises at least two of the following four oligonucleotide probes: two oligonucleotide probes complementary to two different nucleotide sequences of at least 50 nucleotides located within the Replicase 1A or 1B gene of SARS-CoV (Abstract, where the array comprises 60-mers, Table 1, oligo 2, 16, 12, 9, etc. which are directed to the replicase 1A sequence, as evidenced by Marra et al, Figure 1, where the replicase 1A sequence falls between 265-13,398), an oligonucleotide probe complementary to a nucleotide sequence of at least 50 nucleotides located within the N gene of SARS-CoV and an oligonucleotide probe complementary to a nucleotide sequence of at least 50 nucleotides located within the S gene of SARS-CoV (Abstract, where the array comprises 60-

mers, Table 1, oligo 28 and oligo 05, which are directed to spike glycoprotein, as evidenced by Marra et al., Figure 1, where the Spike glycoprotein falls between 21,492-25,259).

With regard to claim 15, Shi teaches an embodiment of claim 4, wherein the label of the immobilization control probe is selected from the group consisting of a chemical, an enzymatic, an immunogenic, a radioactive, a fluorescent, a luminescent and a FRET label (p. 1166, col. 2, where the cDNAs were fluorescently labeled).

With regard to claim 21, Shi teaches an embodiment of claim 2, wherein at least one of the oligonucleotide probes is complementary to a highly expressed nucleotide sequence of SARS-CoV genome (p. 1168, col. 2, 'design of the oligos and microarray' heading, Figure 1 and Table 1, where the specific oligonucleotide sequences complementary to SARS-CoV are included).

With regard to claim 30, Shi teaches an embodiment of claim 1, wherein the support comprises a surface that is selected from the group consisting of a silicon, a plastic, a glass, a ceramic, a rubber, and a polymer surface (p. 1168, col. 1, 'preparation of the 60-mer oligonucleotide microarray heading' where silanized slides were coated with poly lysine prior to the addition of oligonucleotide probes).

Claims 1-21, 23 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. (WO2004/099440; November 2004, 102(e) date May 9, 2003). Li teaches a chip for detection of SARS-CoV sequences (Abstract).

With regard to claim 1, Li teaches a chip for assaying for a coronavirus causing the severe acute respiratory syndrome (SARS-CoV) and a non-SARS-CoV infectious organism,

which chip comprises a support suitable for use in nucleic acid hybridization having immobilized thereon an oligonucleotide probe complementary to a nucleotide sequence of SARS-CoV genome, said nucleotide sequence comprising at least 50 nucleotides (p. 18, lines 12-14, where the probes to target SARS-CoV comprise a sequence of at least 50 to as many as 100 nucleotides or more in length; p. 27, lines 31-32), and one or more of the following oligonucleotide probe(s):

a) an oligonucleotide probe complementary to a nucleotide sequence of a non-SARS-CoV infectious organism causing SARS-like symptoms, said nucleotide sequence comprising at least 50 nucleotides (p. 12, lines 18-26, where there is an oligo complementary to a non-SARS-CoV sequence; p. 16, line 27 to p. 17, line 10, Table 5),

wherein the non-SARS-CoV infectious organism causing SARS-like symptoms is selected from the group consisting of a human coronavirus 229E, a human coronavirus OC43, a human enteric coronavirus, an influenza virus, a parainfluenza virus, a respiratory syncytial virus, a human metapneumovirus, an adenovirus, a mycoplasma pneumonia, a chlamydia pneumonia, a measles virus and a rubella virus (p. 12, lines 18-26, where there is an oligo complementary to a non-SARS-CoV sequence; p. 16, line 27 to p. 17, line 10, Table 5, where the exemplary non-SARS-CoV viruses include human coronavirus 229E, human coronavirus OC43, influenza, parainfluenza);

b) an oligonucleotide probe complementary to a nucleotide sequence of a non-SARS-CoV infectious organism damaging an infectious host's immune system, said nucleotide sequence comprising at least 50 nucleotides,

wherein the non-SARS-CoV infectious organism damaging the human immune system is selected from the group consisting of hepatitis virus, a transfusion transmitting virus (TTV), a

human immunodeficiency virus (HIV), a parvovirus, a human cytomegalovirus (HCMV), an Epstein-Barr virus (EBV) and a *Treponema pallidum*.

With regard to claim 2, Li teaches an embodiment of claim 1, which chip comprises a support suitable for use in nucleic acid hybridization having immobilized thereon at least two oligonucleotide probes complementary to at least two different nucleotide sequences of SARS-CoV genome, each of said two different nucleotide sequences comprising at least 50 nucleotides (p. 12, lines 1-8; p. 18, lines 12-14, where the probes to target SARS-CoV comprise a sequence of at least 50 to as many as 100 nucleotides or more in length; p. 27, lines 31-32).

With regard to claim 3, Li teaches an embodiment of claim 2, wherein the at least two different nucleotide sequences of SARS-CoV genome comprises:

a) a nucleotide sequence of at least 50 nucleotides (p. 18, lines 12-14, where the probes to target SARS-CoV comprise a sequence of at least 50 to as many as 100 nucleotides or more in length; p. 27, lines 31-32) located within a conserved region of SARS-CoV genome and a nucleotide sequence of at least 50 nucleotides located within a variable region of SARS-CoV genome (p. 12, lines 9-17, where the sequence is located within a conserved region of SARS-CoV); or

b) a nucleotide sequence of at least 50 nucleotides (p. 18, lines 12-14, where the probes to target SARS-CoV comprise a sequence of at least 50 to as many as 100 nucleotides or more in length; p. 27, lines 31-32) located within a structural protein coding gene of SARS-CoV genome and a nucleotide sequence of at least 50 nucleotides located within a non-structural protein coding gene of SARS-CoV genome (p. 12, lines 9-17, where the sequence is located within a variable region of SARS-CoV).

With regard to claim 4, Li teaches an embodiment of claim 2, which further comprises:

a) at least one of the following three oligonucleotide probes: an immobilization control probe that is labeled and does not participate in any hybridization reaction when a sample containing or suspected of containing of a SARS-CoV or a non-SARS-CoV infectious organism is contacted with the chip, a positive control probe that is not complementary to any sequence of a SARS-CoV or non-SARS-CoV infectious organism but is complementary to a sequence contained in the sample not found in the SARS-CoV or the non-SARS-CoV infectious organism and a negative control probe that is not complementary to any nucleotide sequence contained in the sample (p. 12, lines 18-26, where there is an oligo complementary to a non-SARS-CoV sequence and includes a positive control probe, a negative control probe and a blank spot); and

b) a blank spot (p. 12, lines 18-26, where there is an oligo complementary to a non-SARS-CoV sequence and includes a positive control probe, a negative control probe and a blank spot).

With regard to claim 5, Li teaches an embodiment of claim 2, which comprises at least two oligonucleotide probes complementary to two different nucleotide sequences of at least 50 nucleotides (p. 18, lines 12-14, where the probes to target SARS-CoV comprise a sequence of at least 50 to as many as 100 nucleotides or more in length; p. 27, lines 31-32), respectively, located within a conserved region of SARS-CoV genome, located within a structural protein coding gene of SARS-CoV genome or located within a non-structural protein coding gene of SARS-CoV genome (p. 12, lines 8-17, where the probes are complementary to a structural coding gene or to a non-structural protein coding gene; p. 12, lines 27-31, where there are at least two probes complementary to two different sequences).

With regard to claim 6, Li teaches an embodiment of claim 5, wherein:

- a) the conserved region of S ARS-CoV genome is a region located within the Replicase 1A or 1B gene or the Nucleocapsid (N-) gene of SARS-CoV (p. 13, lines 1-3, where the region is located in the replicase or nucleocapsid gene);
- b) the structural protein coding gene of SARS-CoV genome is a gene encoding the Spike glycoprotein (S), the small envelope protein (E) or the Nucleocapsid protein (N); or c) the non-structural protein coding gene of SARS-CoV genome is a gene encoding the Replicase 1A or 1B (p. 13, lines 4-6, where the region is located in the spike glycoprotein or nucleocapsid protein).

With regard to claim 7, Li teaches an embodiment of claim 3, wherein the variable region of SARS-CoV genome is a region located within the Spike glycoprotein (S) gene of SARS-CoV (p. 13, lines 4-6, where the variable region is located within the spike glycoprotein).

With regard to claim 8, Li teaches an embodiment of claim 2, which comprises at least two of the following four oligonucleotide probes: two oligonucleotide probes complementary to two different nucleotide sequences of at least 50 nucleotides (p. 18, lines 12-14, where the probes to target SARS-CoV comprise a sequence of at least 50 to as many as 100 nucleotides or more in length; p. 12, lines 31-32) located within the Replicase 1A or 1B gene of SARS-CoV, an oligonucleotide probe complementary to a nucleotide sequence of at least 50 nucleotides located within the N gene of SARS-CoV and an oligonucleotide probe complementary to a nucleotide sequence of at least 50 nucleotides located within the S gene of SARS-CoV (p. 13, lines 14-20, where the chip comprises two of the four probes listed above).

With regard to claim 9, Li teaches an embodiment of claim 8, wherein one of the two different nucleotide sequences located within the Replicase 1A or 1B gene of SARS-CoV comprises a nucleotide sequence that:

- a) hybridizes, under high stringency, with a Replicase 1A or 1B nucleotide sequence, or a complementary strand thereof, that is SEQ ID NO:210 (see Table 2, p. 5 and Table 3, p. 15, where the sequence of PBS00024 is the same as SEQ ID NO:210); or
- b) has at least 90% identity to a Replicase 1A or 1B nucleotide sequence comprising a nucleotide sequence, or a complementary strand thereof, that is SEQ ID NO:210 (see Table 2, p. 5 and Table 3, p. 15, where the sequence of PBS00024 is the same as SEQ ID NO:210).

With regard to claim 10, Li teaches an embodiment of claim 9, wherein one of the two different nucleotide sequences located within the Replicase 1A or 1B gene of SARS-CoV comprises a nucleotide sequence that is SEQ ID NO:210 (see Table 2, p. 5 and Table 3, p. 15, where the sequence of PBS00024 is the same as SEQ ID NO:210).

With regard to claim 11, Li teaches an embodiment of claim 8, wherein the nucleotide sequence located within the N gene of SARS-CoV comprises a nucleotide sequence that:

- a) hybridizes, under high stringency, with a N nucleotide sequence, or a complementary strand thereof, that is SEQ ID NO:225 (see Table 2, p. 6 or Table 3, p. 15, where PBS00040 which is the same as SEQ ID NO:225)
- b) has at least 90% identity to a N nucleotide sequence comprising a nucleotide sequence, or a complementary strand thereof, that is SEQ ID NO:225 (see Table 2, p. 6 or Table 3, p. 15, where PBS00040 which is the same as SEQ ID NO:225).

With regard to claim 12, Li teaches an embodiment of claim 11, wherein the nucleotide sequence located within the N gene of SARS-CoV comprises a nucleotide sequence that is SEQ ID NO:225 (see Table 2, p. 6 or Table 3, p. 15, where PBS00040 which is the same as SEQ ID NO:225).

With regard to claim 13, Li teaches an embodiment of claim 8, wherein the nucleotide sequence located within the S gene of SARS-CoV comprises a nucleotide sequence that:

- a) hybridizes, under high stringency, with a S nucleotide sequence, or a complementary strand thereof, that is set forth in SEQ ID NO:229 (see Table 2, p. 6 or Table 3, p. 15, where PBS00044 which is the same as SEQ ID NO:229)
- b) has at least 90% identity to a S nucleotide sequence comprising a nucleotide sequence, or a complementary strand thereof, that is SEQ ID NO:229 (see Table 2, p. 6 or Table 3, p. 15, where PBS00044 which is the same as SEQ ID NO:229).

With regard to claim 14, Li teaches an embodiment of claim 13, wherein the nucleotide sequence located within the S gene of SARS-CoV comprises a nucleotide sequence that is SEQ ID NO:229 (see Table 2, p. 6 or Table 3, p. 15, where PBS00044 which is the same as SEQ ID NO:229).

With regard to claim 15, Li teaches an embodiment of claim 4, wherein the label of the immobilization control probe is selected from the group consisting of a chemical, an enzymatic, an immunogenic, a radioactive, a fluorescent, a luminescent and a FRET label (p. 16, lines 1-3, where the label on the immobilization control probe can include a variety of labels).

With regard to claim 16, Li teaches an embodiment of claim 4, wherein the non-SARS-CoV sequence is spiked in the sample to be assayed (p. 16, lines 4-8, where non-SARS CoV sequence can be spiked).

With regard to claim 17, Li teaches an embodiment of claim 16, wherein the spiked non-SARS-CoV sequence is a sequence of Arabidopsis organism (p. 16, lines 4-8, where the non-SARS-CoV sequence can be from Arabidopsis).

With regard to claim 18, Li teaches an embodiment of claim 8, which comprises two oligonucleotide probes complementary to two different nucleotide sequences located within the Replicase 1A or 1B gene of SARS-CoV, an oligonucleotide probe complementary to a nucleotide sequence located within the N gene of SARS-CoV, an oligonucleotide probe complementary to a nucleotide sequence located within the S gene of SARS-CoV, an immobilization control probe that is labeled and does not participate in any hybridization reaction when a sample containing or suspected of containing of a SARS-CoV or a non-SARS-CoV infectious organism is contacted with the chip, a positive control probe that is not complementary to any sequence of a SARS-CoV or non-SARS-CoV infectious organism but is complementary to a sequence contained in the sample not found in the SARS-CoV or the non-SARS-CoV infectious organism and a negative control probe that is not complementary to any nucleotide sequence contained in the sample (p. 16, lines 9-19, where the chip includes the embodiment claimed, including two different nucleotide sequences in Replicase, including an immobilization control probe, positive control and negative control).

With regard to claim 19, Li teaches an embodiment of claim 18, which comprises multiple spots of the two oligonucleotide probes complementary to two different nucleotide

sequences located within the Replicase 1B gene of SARS-CoV, the oligonucleotide probe complementary to a nucleotide sequence located within the N gene of SARS-CoV, the oligonucleotide probe complementary to a nucleotide sequence located within the S gene of SARS-CoV, the immobilization control probe, the positive control probe and the negative control probe (p. 16, lines 9-19, where the chip includes the embodiments claimed, including two different nucleotide sequences in Replicase, immobilization control probe, positive control and negative control and includes multiple spots of the oligonucleotide).

With regard to claim 20, Li teaches an embodiment of claim 4, wherein at least one of the oligonucleotide probe comprises, at its 5' end, a poly dT region to enhance its immobilization on the support (p. 18, lines 1-7, where the probes comprise poly dT regions).

With regard to claim 21, Li teaches an embodiment of claim 2, wherein at least one of the oligonucleotide probes is complementary to a highly expressed nucleotide sequence of SARS-CoV genome (p. 18, lines 8-10, where the oligos are complementary to a highly expressed nucleotide sequence).

With regard to claim 23, Li teaches an embodiment of claim 1, wherein the influenza virus is influenza virus A or influenza virus B (Table 5, where the influenza virus includes A, B and C).

With regard to claim 30, Li teaches an embodiment of claim 1, wherein the support comprises a surface that is selected from the group consisting of a silicon, a plastic, a glass, a ceramic, a rubber, and a polymer surface (p. 18, lines 18-20, where the support comprises a surface including silicon, plastic, glass).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi as applied to claims 1-8, 15, 21 and 30 above and further in view of Ruan et al. (2003, The Lancet, 361(9371): 1779-85).

While Shi teaches probes that hybridize with the SARS-CoV genome, Shi does not teach the specific sequence as claimed below.

With regard to claim 9, Ruan teaches an embodiment of claim 8, wherein one of the two different nucleotide sequences located within the Replicase 1A or 1B gene of SARS-CoV comprises a nucleotide sequence that:

a) hybridizes, under high stringency, with a Replicase 1A or 1B nucleotide sequence, or a

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complementary strand thereof, that is SEQ ID NO:210 (see alignment below, between SEQ ID NO:210 and AY283798); or

```

Query   1      TCATAGCTAACATCTTTACTCCTCTTGTC AACCTGTGGGTGCTTTAGATGTGCTGCTT 60
          |||
Sbjct   9256    TCATAGCTAACATCTTTACTCCTCTTGTC AACCTGTGGGTGCTTTAGATGTGCTGCTT
          9315
Query   61      CAGTAGTGGC   70
          |||
Sbjct   9316    CAGTAGTGGC   9325

```

b) has at least 90% identity to a Replicase 1A or 1B nucleotide sequence comprising a nucleotide sequence, or a complementary strand thereof, that is SEQ ID NO:210 (see alignment above, between SEQ ID NO:210 and AY283798).

With regard to claim 10, Ruan teaches an embodiment of claim 9, wherein one of the two different nucleotide sequences located within the Replicase 1A or 1B gene of SARS-CoV comprises a nucleotide sequence that is SEQ ID NO:210 (see alignment above, between SEQ ID NO:210 and AY283798).

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed probes simply represent structural homologs, which are derived from sequences suggested by the prior art as useful for primers and probes for the detection of SARS-CoV, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi as applied to claims 1-8, 15, 21 and 30 above and further in view of Briese et al. (US PgPub 20040265796; December 2004, 102(e) date April 17, 2003).

While Shi teaches probes that hybridize with the SARS-CoV genome, Shi does not teach the specific sequence as claimed below.

With regard to claim 11, Briese teaches an embodiment of claim 8, wherein the nucleotide sequence located within the N gene of SARS-CoV comprises a nucleotide sequence that:

a) hybridizes, under high stringency, with a N nucleotide sequence, or a complementary strand thereof, that is SEQ ID NO:225 (see alignment below between SEQ ID NO:1 of Briese and with SEQ ID NO:225); or

```
Qy      1  GAGGTGGTGAACCTGCCCTGCGGCTATTGCTGCTAGACAGATTGAACGAGTTGAGAGCA  60
         | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      255 GAGGTGGTGAACCTGCCCTGCGGCTATTGCTGCTAGACAGATTGAACGAGTTGAGAGCA  314

Qy      61  AAGTTTCTGG  70
         | | | | | | |
Db      315 AAGTTTCTGG  324
```

b) has at least 90% identity to a N nucleotide sequence comprising a nucleotide sequence, or a complementary strand thereof, that is SEQ ID NO:225 (see alignment above between SEQ ID NO:1 of Briese and with SEQ ID NO:225).

With regard to claim 12, Briese teaches an embodiment of claim 11, wherein the nucleotide sequence located within the N gene of SARS-CoV comprises a nucleotide sequence that is SEQ ID NO:225 (see alignment above between SEQ ID NO:1 of Briese and with SEQ ID NO:225).

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed probes simply represent structural homologs, which are derived from sequences suggested by the prior art as useful for primers and probes for the detection of SARS-CoV, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi as applied to claims 1-8, 15, 21 and 30 above and further in view of Vilalta et al. (WO2005021707; March 2005; with priority to 60/470820, effective date May 16, 2003).

While Shi teaches probes that hybridize with the SARS-CoV genome, Rong does not teach the specific sequence as claimed below.

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With regard to claim 13, Vilalta teaches an embodiment of claim 8, wherein the nucleotide sequence located within the S gene of SARS-CoV comprises a nucleotide sequence that:

a) hybridizes, under high stringency, with a S nucleotide sequence, or a complementary strand thereof, that is set forth in SEQ ID NO:229 (see alignment below between SEQ ID NO:3 of Vilalta); or

```
Qy      1  CACCTGGAACAAATGCTTCATCTGAACTGCTGTTCTATATCAAGATGTTAACTGCACTG  60
        |||
Db      1754 CACCTGGAACAAATGCTTCATCTGAACTGCTGTTCTATATCAAGATGTTAACTGCACTG  1813

Qy      61  ATGTTTCTAC  70
        |||
Db      1814 ATGTTTCTAC  1823
```

b) has at least 90% identity to a S nucleotide sequence comprising a nucleotide sequence, or a complementary strand thereof, that is SEQ ID NO:229 (see alignment above between SEQ ID NO:3 of Vilalta).

With regard to claim 14, Vilalta teaches an embodiment of claim 13, wherein the nucleotide sequence located within the S gene of SARS-CoV comprises a nucleotide sequence that is SEQ ID NO:229 (see alignment above between SEQ ID NO:3 of Vilalta).

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary

skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed probes simply represent structural homologs, which are derived from sequences suggested by the prior art as useful for primers and probes for the detection of SARS-CoV, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi as applied to claims 1-8, 15, 21 and 30 above and further in view of Martoglio et al. (Molecular Medicine, 2000, 6(9):750-765).

With regard to claim 18, Shi teaches an embodiment of claim 8, which comprises two oligonucleotide probes complementary to two different nucleotide sequences located within the Replicase 1A or 1B gene of SARS-CoV (Table 1, oligo 2, 16, 12, 9, etc. which are directed to the replicase 1A sequence, as evidenced by Marra et al, Figure 1, where the replicase 1A sequence falls between 265-13,398), an oligonucleotide probe complementary to a nucleotide sequence located within the N gene of SARS-CoV (Table 1, oligo 27 and oligo 18, which are directed to the nucleocapsid or N gene, as evidenced by Marra, et al., Figure 1, where the N gene falls between 28,120-29,388), an oligonucleotide probe complementary to a nucleotide sequence located within the S gene of SARS-CoV, a negative control probe that is not complementary to any nucleotide sequence contained in the sample (Figure 1, where there were negative control spots included and where there were empty control spots or blank spots).

With regard to claim 19, Shi teaches an embodiment of claim 18, which comprises multiple spots of the two oligonucleotide probes complementary to two different nucleotide

sequences located within the Replicase 1A or 1B gene of SARS-CoV (Table 1, oligo 2, 16, 12, 9, etc. which are directed to the replicase 1A sequence, as evidenced by Marra et al, Figure 1, where the replicase 1A sequence falls between 265-13,398), the oligonucleotide probe complementary to a nucleotide sequence located within the N gene of SARS-CoV (Table 1, oligo 27 and oligo 18, which are directed to the nucleocapsid or N gene, as evidenced by Marra, et al., Figure 1, where the N gene falls between 28,120-29,388), the oligonucleotide probe complementary to a nucleotide sequence located within the S gene of SARS-CoV (Table 1, oligo 28 and oligo 05, which are directed to spike glycoprotein, as evidenced by Marra et al., Figure 1, where the Spike glycoprotein falls between 21,492-25,259), and the negative control probe (Figure 1, where there were negative control spots included and where there were empty control spots or blank spots).

Regarding claims 16-17, Shi does not teach the spiking of a non-SARS-CoV sequence in the sample and also does not teach that the sequence is of Arabidopsis origin. Regarding claims 18 and 19, Shi does not teach the inclusion of an immobilization control probe or a positive control probe. Martoglio teaches the inclusion of these probes in a microarray format.

With regard to claim 16-17, Martoglio teaches spiking a non-SARS-CoV sequence in the sample to be assayed and that the sequence is of Arabidopsis origin (p. 752, col. 1-2, where the samples were spiked with an Arabidopsis cytochrome cDNA as a control for labeling and hybridization; see also p. 753, 'processing hybridization signals' heading).

With regard to claim 18-19, Martoglio teaches an immobilization control probe and a positive control probe (p. 752, col. 1-2, where the samples were spiked with an Arabidopsis

cytochrome cDNA as a control for labeling and hybridization; see also p. 753, 'processing hybridization signals' heading).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have included the additional controls for microarray normalization taught by Martoglio to the array for SARS-CoV sequences taught by Shi to arrive at the claimed invention with a reasonable expectation for success. As taught by Martoglio, "To account for potential differences in probe labeling, each data set was normalized with respect to the corresponding mean signal intensity of *Arabidopsis thaliana* cytochrome c554 cDNA added to each probe as direct internal controls, as described above" (p. 753, 'processing hybridization signals' heading). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to have included the additional controls for microarray normalization taught by Martoglio to the array for SARS-CoV sequences taught by Shi to arrive at the claimed invention with a reasonable expectation for success.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shi as applied to claims 1-8, 21 and 30 above and further in view of Saiki et al. (PNAS, 1989, vol. 86, p. 6230-6234).

With regard to claim 20, Saiki teaches an embodiment of claim 4, wherein at least one of the oligonucleotide probe comprises, at its 5' end, a poly dT region to enhance its immobilization on the support (p. 6230, 'tailing of oligonucleotides' heading, where the oligos were tailed with poly dT prior to immobilization).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the teachings of tailed oligonucleotides to the array or chip of Shi to arrive at the claimed invention with a reasonable expectation for success. As taught by Saiki, "in a single hybridization reaction, an entire series of sequences could be examined simultaneously". Saiki also teaches "the poly(dT) tail would be a larger target for UV crosslinking and should preferentially react with the nylon" (p. 6230, col. 1). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to have incorporated the teachings of tailed oligonucleotides to the array or chip of Shi to arrive at the claimed invention with a reasonable expectation for success.

Claims 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi as applied to claims 1-8, 15, 21 and 30 above and further in view of Marra et al. (Science, 2003, vol. 300, p. 1399-1404; epub May 2003).

With regard to claim 23, Marra teaches an embodiment of claim 1, wherein the influenza virus is influenza virus A or influenza virus B (Figure 1, legend, where a variety of additional viruses and organisms are listed as related to SARS-CoV phylogenetically).

With regard to claim 24, Marra teaches an embodiment of claim 22, wherein the parainfluenza virus is selected from the group consisting of parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3 and parainfluenza virus 4 (Figure 1, legend, where a variety of additional viruses and organisms are listed as related to SARS-CoV phylogenetically).

With regard to claim 27, 28, Marra teaches an embodiment of claim 1, wherein the HIV is HIV-1 (Figure 1, legend, where a variety of additional viruses and organisms are listed as related to SARS-CoV phylogenetically).

With regard to claim 26, Marra teaches an embodiment of claim 25, wherein the hepatitis virus is selected from the group consisting of hepatitis virus A (HAV), hepatitis virus B (HBV), hepatitis virus C (HCV), hepatitis virus D (HDV), hepatitis virus E (HEV) and hepatitis virus G (HGV) (Figure 1, legend, where a variety of additional viruses and organisms are listed as related to SARS-CoV phylogenetically).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have extended the teachings of Shi to include the additional non-SARS-CoV infectious organisms disclosed by Marra to arrive at the claimed invention with a reasonable expectation for success. While Marra does not teach the inclusion of these various non-SARS-CoV organisms in a microarray format, Marra does establish the phylogenetic relationship between the SARS-CoV genome, and particular coding features within the genome as compared to these non-SARS-CoV sequences. As Shi already includes a probe complementary to a non-SARS-CoV sequence, one of ordinary skill in the art at the time the invention was made would have been motivated to have extended the teachings of Shi to include the additional non-SARS-CoV infectious organisms disclosed by Marra to arrive at the claimed invention with a reasonable expectation for success.

Claims 24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (WO2004/099440; November 2004, 102(e) date May 9, 2003) as applied to claims 1-21, 23

and 30 above and further in view of Marra et al. (Science, 2003, vol. 300, p. 1399-1404; epub May 2003). Li teaches a chip for detection of SARS-CoV sequences (Abstract).

With regard to claim 24, Marra teaches an embodiment of claim 22, wherein the parainfluenza virus is selected from the group consisting of parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3 and parainfluenza virus 4 (Figure 1, legend, where a variety of additional viruses and organisms are listed as related to SARS-CoV phylogenetically).

With regard to claim 27, 28, Marra teaches an embodiment of claim 1, wherein the non-SARS-CoV infectious organism damaging an infectious host's immune system is selected from the group consisting of a hepatitis virus, a transfusion transmitting virus (TTV), a human immunodeficiency virus (HIV), a parvovirus, a human cytomegalovirus (HCMV), an Epstein-Barr virus (EBV) and and *Treponema palidum* (Figure 1, legend, where a variety of additional viruses and organisms are listed as related to SARS-CoV phylogenetically).

With regard to claim 26, Marra teaches an embodiment of claim 25, wherein the hepatitis virus is selected from the group consisting of hepatitis virus A (HAV), hepatitis virus B (HBV), hepatitis virus C (HCV), hepatitis virus D (HDV), hepatitis virus E (HEV) and hepatitis virus G (HGV) (Figure 1, legend, where a variety of additional viruses and organisms are listed as related to SARS-CoV phylogenetically).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have extended the teachings of Li to include the additional non-SARS-CoV infectious organisms disclosed by Marra to arrive at the claimed invention with a reasonable expectation for success. While Marra does not teach the inclusion of these various non-SARS-CoV organisms in a microarray format, Marra does establish the phylogenetic

relationship between the SARS-CoV genome, and particular coding features within the genome as compared to these non-SARS-CoV sequences. As Li already includes a probe complementary to a non-SARS-CoV sequence, one of ordinary skill in the art at the time the invention was made would have been motivated to have extended the teachings of Li to include the additional non-SARS-CoV infectious organisms disclosed by Marra to arrive at the claimed invention with a reasonable expectation for success.

Response to Arguments

Applicant's arguments filed July 6, 2009 have been fully considered but they are not persuasive.

Applicant requests that the obviousness type double patenting rejection be held in abeyance. This argument has been considered, but is not persuasive because the double patenting rejection is not the only outstanding rejection still pending in the application.

Applicant traverses the rejection of claims as being anticipated by Shi and argues "Shi teaches that oligo 10 in Table 1 is a common sequence of SARS-CoV, bovine coronavirus, murine hepatitis virus, rat coronavirus and avian infectious bronchitis virus)" and that "none of the non-SARS-CoV organisms taught in Shi - namely, bovine coronavirus, murine hepatitis virus, rat coronavirus and avian infectious bronchitis virus - is recited in claim 1 as amended". Applicant concludes "Shi does not teach a SARS diagnostic chip comprising one or more oligonucleotide probe(s) complementary to a nucleotide sequence of any of the non-SARS-CoV infectious organisms recited in claim 1" (p. 19-20 of remarks).

These arguments have been considered, but are not persuasive. Contrary to Applicant's arguments, Shi teaches a hepatitis virus, a virus which is included in Claim 1, step b, as a virus which represents a non-SARS-CoV infectious organism damaging to the human immune system. As evidenced by Koettler, the murine hepatitis virus is capable of infecting human cells, which meets the limitation of the claim. Therefore, the rejection over Shi is maintained as amended.

Applicant traverses the rejection of claims 9-10 as being obvious over Shi in view of Ruan; claims 11-12 as being obvious over Shi in view of Briese; claims 13-14 as being obvious over Vilalta; claims 16-19 as being obvious over Shi in view of Martoglio; claim 20 as being obvious over Shi in view of Saiki.

Applicant reiterates the argument asserted over Shi above, and asserts that none of the secondary references cure the deficiencies in Shi. These arguments are not persuasive for the same reasons as asserted above. The rejections are maintained.

Applicant traverses the rejection of claims 22-28 as being obvious over Shi in view of Marra. Applicant argues "contrary to the Office's position that it would have been obvious 'to have extended the teachings of Shi to include the additional non-SARS-CoV infectious organisms disclosed by Marra', neither reference teaches or even suggests the idea of combining SARS-CoV and non-SARS-CoV diagnostics on one chip" and that "it would have been impossible to distinguish a SARS-CoV infection from a non-SARS CoV infection using the diagnostic array of Shi" (p. 31 of remarks).

In response to applicant's argument that the chip could not distinguish a SARS-CoV infection from a non-SARS-CoV infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In this case, claim 1 merely requires that the claimed chip includes a probe to a SARS-CoV sequence, and at least one probe which is complementary to a non-SARS-CoV infectious organism. The claim does not require that this secondary probe does not co-hybridize to a SARS-CoV sequence. Therefore, there is no structural difference between the claimed chip and the chip taught by Shi and Applicant's arguments are not persuasive and the rejection is maintained.

Relevant Prior art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zhang et al. (Meth. Molec. Med, 2005, 114:59-78, IDS reference) teaches detection of SARS Co-V sequences using microarray detection. Affymetrix Press release (May 6, 2003, pages 1-2) discloses a new GeneChip™ CustomSeq™ SARS Pathogen detection and resequencing array (p. 1).

Conclusion

All claims stand rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephanie K. Mummert/
Patent Examiner, Art Unit 1637

SKM